



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Characterization of Risk of HIV and HIV Outcomes in the Brazilian Sickle Cell Disease (SCD) Population and Comparison of SCD Outcomes Between HIV Sero-Positive and Negative SCD (NHLBI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on June 8, 2015 (80 FR 32388) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

DATES: Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge Center, Suite 9142, 6701 Rockledge Drive, Bethesda, MD 20892, or call 301- 435-0065, or E-mail your request, including your address to: glynnsa@nhlbi.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Characterization of risk of HIV and HIV outcomes in the Brazilian Sickle Cell Disease (SCD) population and comparison of SCD outcomes between HIV sero-positive and negative SCD patients 0925-NEW, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: The National Heart, Lung, and Blood Institute (NHLBI) Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) program conducts research focused on the safety of the blood supply, the patients who are in need of transfusions, and the epidemiology of transfusion-transmissible infections such as human immunodeficiency virus (HIV). Sickle cell disease (SCD) is a blood disorder that affects thousands of people in the United States and Brazil. Many patients with SCD need to be chronically transfused with red blood cells and the REDS-III research program has established in Brazil a cohort of patients with SCD to study transfusion outcomes and infectious diseases such as HIV in the SCD population.

Sickle cell disease predominantly affects persons with sub-Saharan Africa and other malaria-endemic regions ancestry because people who carry one sickle cell disease gene (you need 2 to have sickle cell disease) have a survival advantage for malaria. Sub-Saharan Africa, where most people with SCD in the world live, remains one of the regions most severely affected

by HIV, with nearly 1 in every 20 adults living with the virus. In the United States, HIV also disproportionately affects persons with African ancestry. Despite the diseases' occurrence in similar populations and the fact that both HIV and SCD are independent predictors of outcomes such as stroke, there is a lack of data to evaluate if patients with SCD and HIV have different illnesses than patients who have SCD- or HIV-only. The proposed study will seek to understand the risk of HIV in the SCD population, describe HIV outcomes in patients with SCD and compare SCD complications between HIV-positive and HIV-negative patients with SCD using the infrastructure established by the REDS-III SCD Cohort study.

The limited studies focused on HIV in SCD have suggested that HIV may not occur as frequently in patients with SCD as in people who do not have SCD. While it has been hypothesized that perhaps SCD pathophysiology has a unique effect on HIV infection or replication, none of the studies have adequately measured risk factors for HIV in patients with SCD. The first objective of the proposed study is to compare HIV risk factors between 150 patients with SCD (cases) randomly selected from the REDS-III SCD Cohort study and 150 individuals without SCD (controls) from a demographically similar population. An assessment that has been well validated in previous studies has been modified for the SCD population and will be used to collect data regarding HIV risk behaviors. The second objective of the proposed study will seek to enroll approximately 25 patients with SCD and HIV who consent to have detailed information regarding their diseases retrieved from their medical records. This will allow for an in-depth evaluation of how patients with both diseases fare. Additionally, patients who have SCD but not HIV will be compared to patients who have both diseases to better understand how one disease affects the other disease. Information on the HIV-negative patients with SCD has already been collected because they participated in the REDS-III SCD Cohort

study. This study will provide critical information to guide the management and future research for patients with HIV and SCD in Brazil, the United States, and worldwide.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 325.

Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Objective 1 Risk Factor Informed Consents	Adult SCD cases and controls	300	1	15/60	75
Objective 2 Risk Factor Informed Consent	Adult previously enrolled REDS-II and III HIV SCD patients	25	1	15/60	6
Objectives 1 and 2 Risk Factor Assessment	Adult SCD cases and controls, and Adult previously enrolled REDS-II and III HIV SCD patients	325	1	45/60	244

Dated: September 8, 2015.

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National Institutes of Health.

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